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Jihad A. Mustapha

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Vista IP Law Group LLP
2040 MAIN STREET, 9TH FLOOR
IRVINE, CA 92614

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This action is in response to applicant's amendment received on 11/16/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3-4, 15-17, 24-31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lam** (U.S. Patent No. **5,607,444**).

Lam discloses in fig. 6 a method whereby a stent is placed such that its more expandable proximal end is placed in a primary vessel and the distal portion is placed in a secondary vessel. The stent is expanded by a balloon used to initially expand the proximal portion of the stent with a toroidal portion to form a flange in the primary vessel and fully inflating the balloon to expand the stent to support the secondary vessel with an ovoid distal portion. The toroidal proximal portion of the balloon expands more than the distal portion. The struts 27 are longer than those of the rest of the knitted or braided stent.

Lam does not expressly teach initially inflating the expandable member such that the proximal portion is inflated without fully inflating the distal balloon portion, thereby

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flaring the proximal stent portion, and fully inflating the expandable member to deploy the distal stent portion within the ostial branch. In other words, Lam does not explicitly teach the step of inflating the proximal portion of the expandable member preceding the step of fully inflating the distal portion of the expandable member, as well as inflating a distal end of the distal portion of an expandable member to thereby trap plaque within the stent. However, Lam teaches using various sized and shaped balloon segments to deploy the ostial stent which may be at different degrees of inflation, and that the flared proximal portion may be expanded before, after, or simultaneously with the distal portion of the stent (col. 7, lines 10-30). It would have been obvious to one of ordinary skill in the art at the time of invention to initially inflate the expandable portion to expand the proximal portion before fully inflating the distal portion in order to ensure proper “capping” of the flared portion for repair of the diseased portion of the bifurcated vessel. A proximal balloon portion being symmetrical shaped about the longitudinal axis of the stent when fully expanded is also not expressly disclosed. However, Lam contemplates a balloon catheter that conforms to an asymmetrical bifurcated vessel, and that “various sized and shaped balloon segments,” as mentioned above, may be utilized to conform to the shape of the bifurcation in order to properly cap the flaring portion of the ostial stent, and therefore having a symmetrical proximal portion of the expanding member about the longitudinal axis of the stent would have been obvious.

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3. Claims 7-8, 10-11, 19-23, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vardi et al.** (U.S. Patent No. **6,210,429**) or **Vardi et al.** (U.S. Patent No. **6,325,826**) in view of **Lam** (U.S. Patent No. **5,607,444**).

Both Vardi references disclose in fig. 6 a-g a method comprising a first step whereby a first stent is placed in an inlet portion and one outlet portion of a bifurcated vessel. The stent is expanded to support these vessel sections. Then a second stent is inserted into the second outlet portion through an aperture in the side wall of the first stent such that it supports the second vessel portion while its proximal end which is more expandable is expanded with a balloon having a more expandable portion in order to cause it to obtain a larger flange-like portion which expands and interlocks inside the first stent around the periphery of the aperture. The flanges are struts longer than the struts making up the rest of the stent (each strut can be referred to as extending from one intersection with other struts to the next intersection with another strut). It also appears that in figs. 6d-e when the stent 15 is initially deployed, the distal end of the expandable member is inflated to thereby trap plaque within the stent.

However, Vardi does not expressly disclose initially expanding a proximal portion of the expandable member to expand the proximal portion of the second stent and expanding a distal end of the expandable member without fully inflating a distal portion of the expandable member, thereby trapping plaque within the second stent. However, as mentioned above, Lam teaches using various sized and shaped balloon segments to deploy an ostial stent which may be at different degrees of inflation, and that the flared proximal portion may be expanded before, after, or simultaneously with the distal

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portion of the stent (col. 7, lines 10-30). It would have been obvious to one of ordinary skill in the art at the time of invention to initially inflate the expandable portion to expand the proximal portion before partially or fully inflating the distal portion in order to ensure proper “capping” of the flared portion for repair of the diseased portion of the bifurcated vessel. For instance, in Figure 8 of Lam, the proximal portion of the balloon may be initially inflated to cap the flange portion 25 of the ostial stent, and the distal portion of the balloon may be partially inflated (such as the middle balloon portion) in order to ensure proper capping of the flared portion, then followed by the opposite end portion of the balloon being inflated in order to fully expand the expandable member.

Response to Arguments

4. Applicant's arguments with respect to claims 3-4, 7-8, 10-11, 15-17, 19-32, and 34-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731